REMARKS

The Office Action dated April 14, 2004 presents the examination of claims 1, 3-6, 12, and 13. The Examiner is reminded that claim 4 was canceled in the Reply under 37 C.F.R. § 1.111 filed on March 18, 2004. Claim 5 is canceled herein. Claims 1, 6, 12, and 13 are amended. Support for the recitation of "the ratio of residual BNP immunoreactivity is 50% or more after 24 hours standing at 25°C" is found in the specification, such as on page 8, line 24 and in Example 3 on page 8, line 26. Support for the recitation of "excluding the addition of any inhibiting agents" is found in the specification, such as on page 2, lines 3-6 and page 4, lines 18-19. Upon entry of this Reply, claims 1, 3, 6, 12, and 13 will be pending. No new matter is inserted into the claims.

Rejection under 35 U.S.C. § 102

The Examiner rejects claims 1, 3-6, 12, and 13 under 35 U.S.C. § 102(b) for allegedly being anticipated by Lindberg et al. (*Pharmacology & Toxicology*) and Clerico et al. (*Clinical Chemistry*). Claim 4 was canceled in the Reply filed March 18, 2004, and claim 5 is canceled herein, thus rendering rejection of these claims moot. Applicants respectfully traverse the rejection applied to the pending claims. Reconsideration of the claims and

withdrawal of the instant rejection are respectfully requested.

The cited references disclose that inhibiting agents must be added to a specimen for suppressing the degradation of ANP. Both references fail to disclose or teach that the degradation of BNP in a specimen is inhibited by placing the specimen into a container made of or coated with a material selected from the group consisting of silicone and plastics. Therefore, the present invention is not anticipated by the references cited by the Examiner.

In the outstanding Office Action, the Examiner argues that Claims 1, 3, 6, 12, and 13 do not exclude the addition of any inhibiting agents, that the claims have been amended from "consisting of" to "comprising," and that the claims do not specify any amount of inhibiting or purity of BNP. The claims, as amended, recite that the addition of any inhibiting agent is excluded, and that the ratio of BNP immunoreactivity is 50% or more after 24 hours standing at 25°C. Lindberg et al. and Clerico et al. fail to teach that the degradation of BNP in a specimen can be inhibited without inhibiting agents, or that the degradation is inhibited to such an extent that residual BNP immunoreactivity is 50% or more after 24 hours at 25°C.

Furthermore, and as noted by the Examiner, Lindberg et al. describes the loss of recovery of ANP at different concentrations in different containers which include siliconized glass and plastic. As noted in the Reply under 37 C.F.R. § 1.111 filed March 18, 2004, the ANP utilized by Lindberg et al. is purified, such that the specimens studied by Lindberg et al. are not bodily samples.

For this reason, the skilled artisan could not extrapolate from Lindberg et al. that the degradation of BNP in a specimen can be inhibited by using a container made of or coated with a material selected from the group consisting of silicone and plastics since there are no substances present in the samples studied by Lindberg et al. which would degrade BNP or ANP in the first place.

Lindberg et al. never discloses or teaches that the degradation of BNP in a specimen can be inhibited by placing the specimen into a container made of or coated with a material selected from the group consisting of silicone and plastics. Therefore, the present invention is not anticipated by Lindberg et al.

Clerico et al. discloses that the degradation of ANP can be avoided by (1) separating plasma from a blood sample, (2) adding a protease inhibitor, aprotinin, and (3) storing the plasma at low

temperatures. As noted by the Examiner, Clerico discloses a sample without aprotinin (page 1629, first column). However, unlike the present invention, Clerico et al. concludes that aprotinin is **needed** for inhibiting the degradation of ANP. Clerico et al. states that after an incubation of thirty minutes at 37°C, the specimen without protease inhibitors showed 70.2% degradation. Thus, Clerico et al. fails to disclose that residual BNP immunoreactivity is 50% or more even when aprotinin is not added to the specimen.

In summary, Lindberg et al. and Clerico et al. fail to anticipate the present invention under 35 U.S.C. § 102. Withdrawal of the instant rejection is therefore respectfully requested.

Title

The Examiner states a new, more descriptive title is required. In response to the Examiner's remarks, Applicants amend the title accordingly. Thus, the instant objection is overcome.

Abstract

The Examiner objects to the abstract for legal phraseology. In response to the Examiner's remarks, Applicants submit a modified abstract herewith. Thus, the instant objection is overcome.

Conclusion

Applicants respectfully submit that the pending claims define patentable subject matter such that this application should be placed into condition for allowance. Early and favorable action on the merits of the present application is thereby requested.

If there are any minor matters precluding allowance of the present application which may be resolved by a telephone discussion, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____ #32,868
for Raymond C. Stewart, #21,066

RCS/KLR:gmh
0032-0254P

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

ABSTRACT

A method for inhibiting the degradation of mammalian natriuretic peptides, in particular BNP, by using containers wherein the face coming into contact with specimens are made of silicone or plastics. This material inhibits the activation of a substance, which in turn, degrades the peptides. This method makes it possible to collect specimens for measuring natriuretic peptides stably and conveniently. Also provided is a method for measuring natriuretic peptides by using these containers.